Technical considerations in diagnostics implementation:

Training, quality assurance and maintenance considerations

Heidi Albert
Senior Technical Officer

NIH TB/HIV Diagnostics Meeting

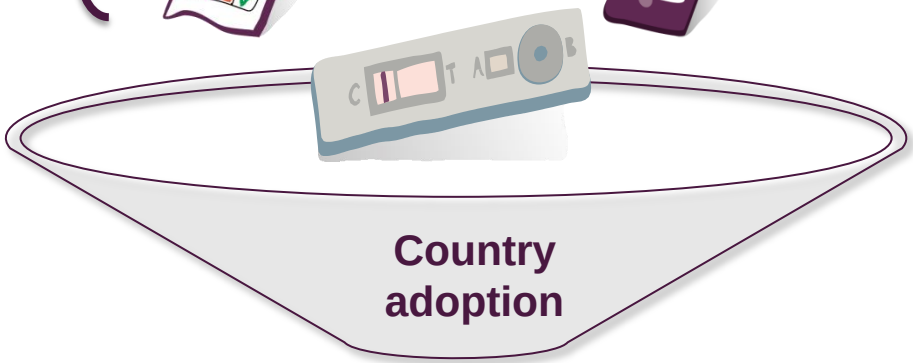
Cape Town, South Africa, 22-23 Sept 2014

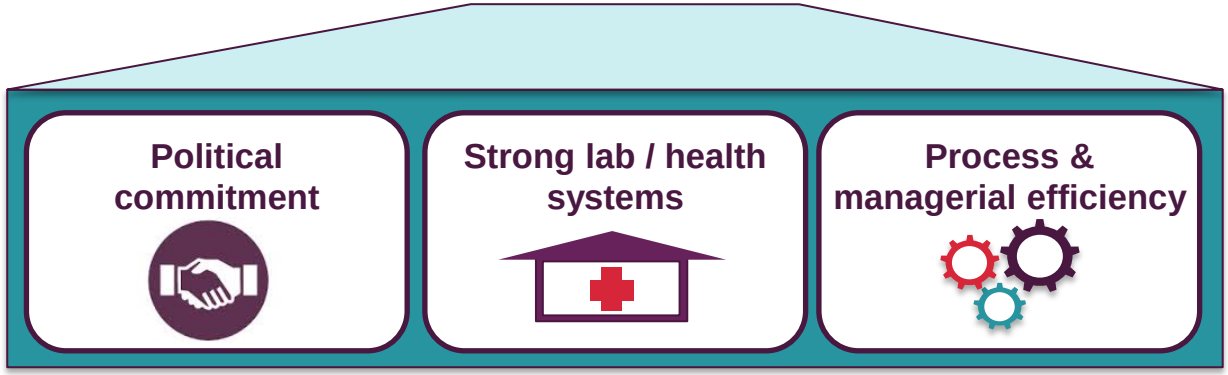
Three-pronged approach to accelerate diagnostics uptake

1. Ensure holistic solutions tailored to specific country needs are in place

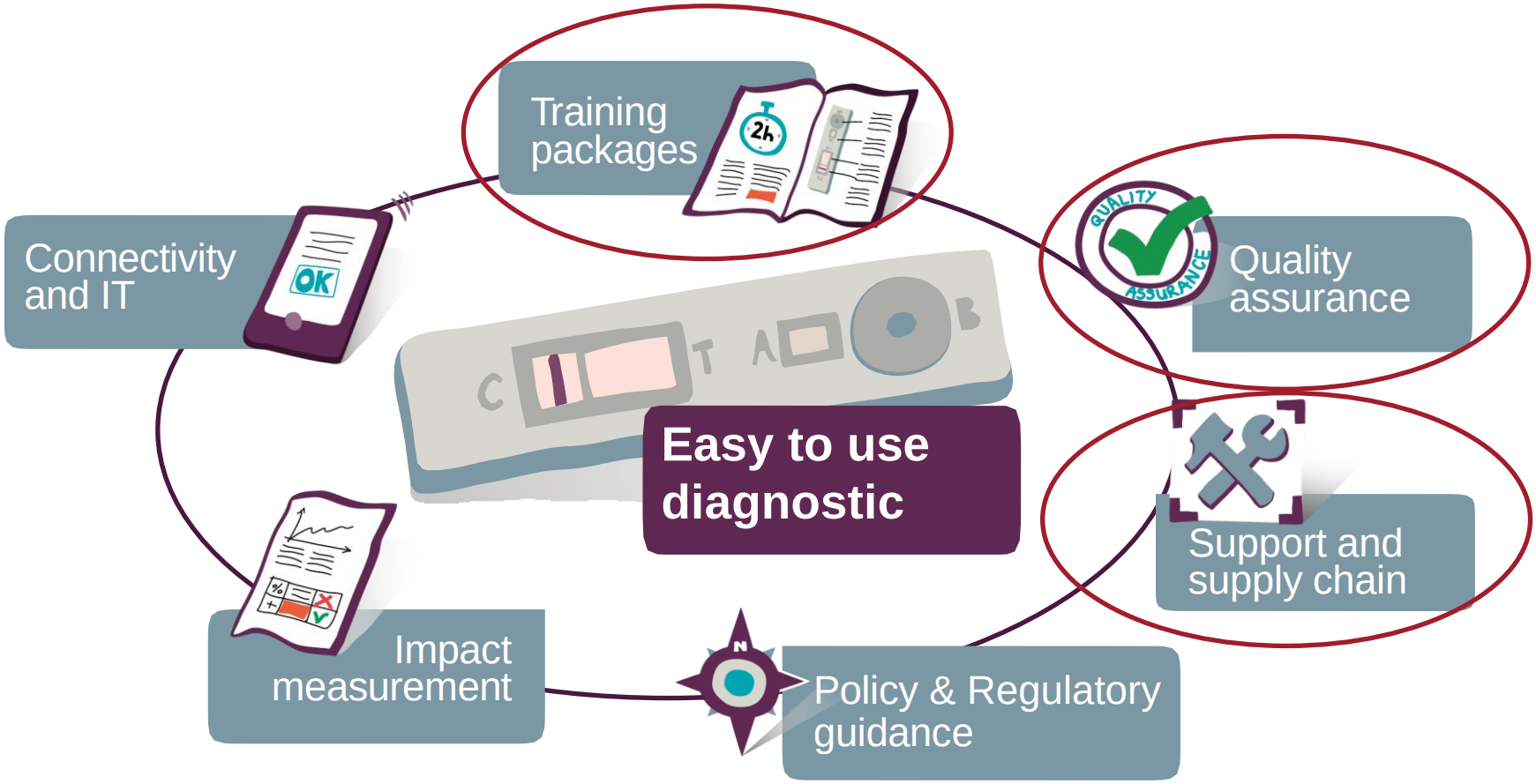
2. Support development of country implementation plans for solutions

3. Strengthen country capabilities to implement and capture benefit of solutions





Comprehensive diagnostic solutions



Lessons learned from Xpert introduction

		2010	2011	2012	2013	2014
Test	Xpert	Launch				Being used in 108 high burden countries
Solution elements	Policy & regulatory guidance	Policy endorsement at unprecedented speed (2 years after design lock / trial start)				Expanded guidance for pediatric & extrapulmonary TB
	Quality assurance	Strong built-in controls	Calibration tool	Validation panels		Remote monitoring
	Support & supply chain	Clear procurement system but long time to repair / replacement				Clear warranty conditions & coverage
	Impact measure-ment	Strong trial data informed rapid policy (w/some impact data)	Early rollout not accompanied by data collection & feedback on implementation			Scarce impact data available; only from trials (not routine collection)
	Connectivity & IT	Connectivity to lab management information systems		First independent IT tools to enable data transfer, mobile use		Chance to reach potential re: linkage to care & connectivity by 2015
	Training & user manuals	1st implementation & basic training guide		More complete job aids & training package		Comprehensive online training

Key	Not available	Partially available but doesn't fully meet need	Meets the need

WHO Policy update and Implementation Manual

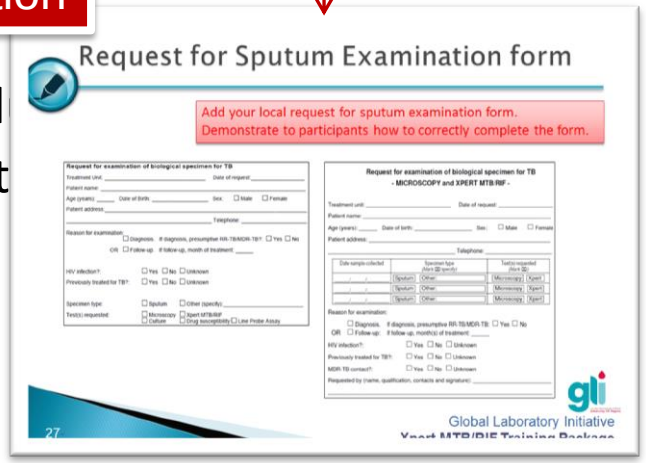
Including:

- Updated guidance on selection of target patient groups and positioning of machines
- Improved budgeting guidance
- Annex of SOPs for processing extrapulmonary specimens

GLI training package

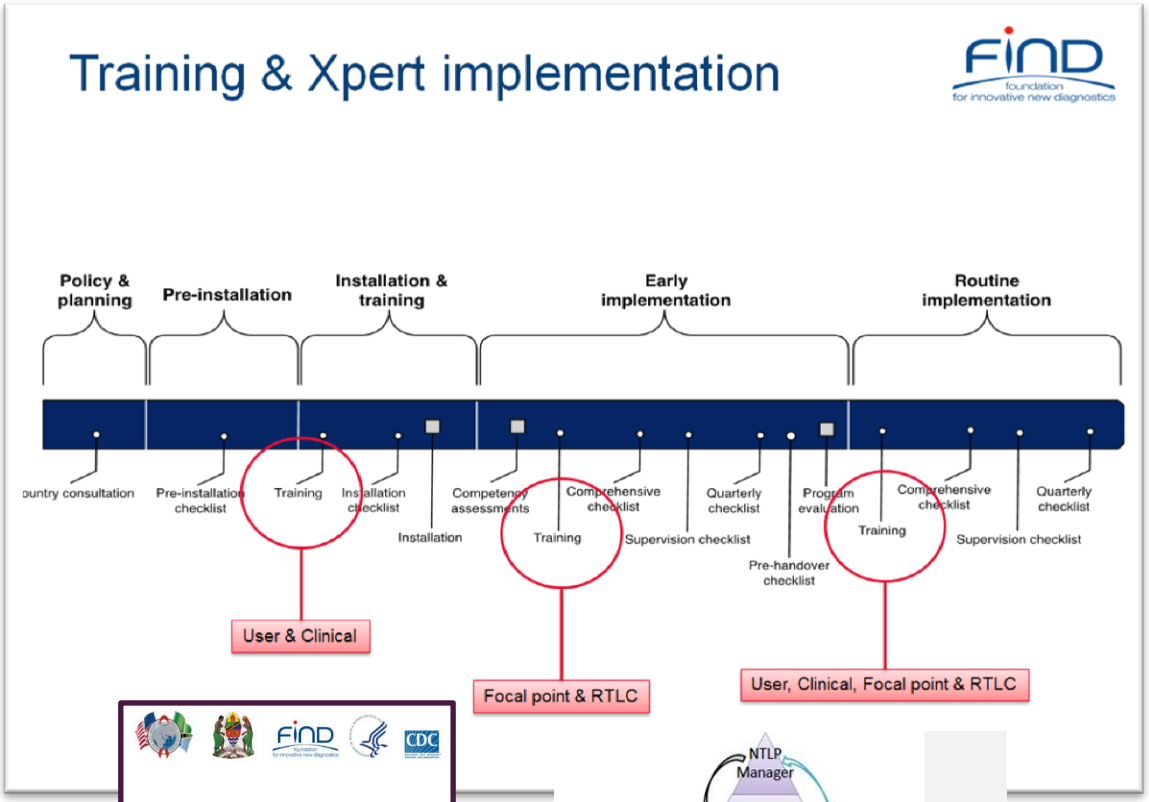
- GLI partners, including CDC, FIND, USAID, KNCV and WHO, have developed **training modules** on Xpert MTB/RIF, combining modules and products of FIND, KNCV and Cepheid
- Modules:
  - Overview of TB and TB diagnostics
  - Biosafety
  - Collection and transportation of specimens
  - Supplies management
  - Installation
  - GeneXpert technology and Xpert MTB/RIF proced
  - Results interpretation and database management
  - Recording and reporting
  - Troubleshooting
  - Maintenance
  - Clinical guide to Xpert MTB/RIF
  - **Quality assurance**

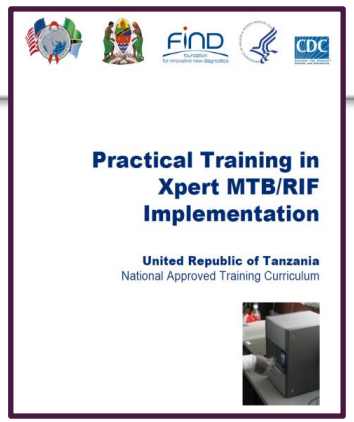
Country customisation

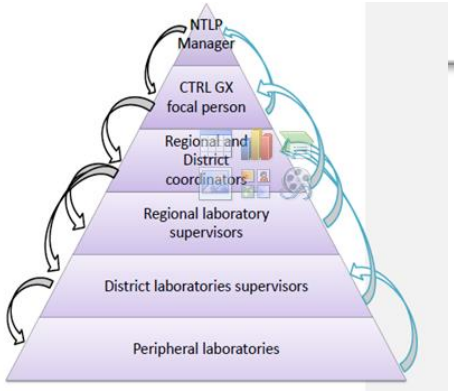


Access them here: www.stoptb.org/wg/gli/

Training







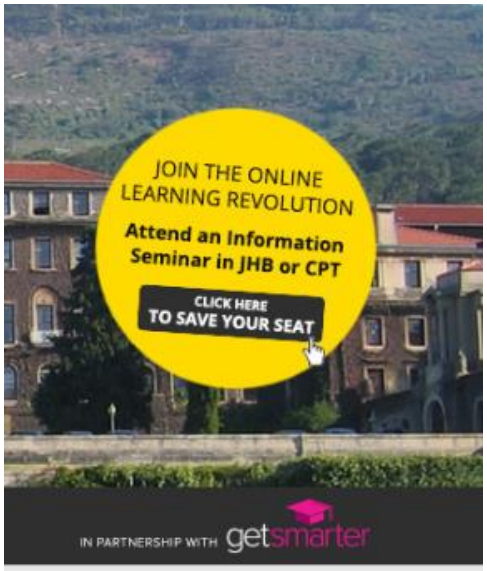
User
Clinical
Focal point (expert “super” users)
RTLC (regional supervisors)

The RTLC training is intended to **provide learners with the practical skills required to perform the Xpert MTB/RIF test assessments**; at least 50% of the RTLC training is **practical**, and includes an **onsite supervision visit**.

Training: blending traditional and modern approaches

- **A slide set is not enough**
- **Adult education principles**
- **Selection, training (and ongoing mentoring) of trainers - teachback**
- **Practical, task-based approach**
- **Competency assessment/certification of trainers and users**
- **Training matched to job function**

  Train the right people, design the right training
- **Refresher training**
- **Updates, *e.g.* extrapulmonary TB, change in algorithm**
- **Online/mobile training options**
- **Training planning and logistics management**



Key Components of Xpert MTB/RIF Quality Assurance Program

Environment

Safe and functional

Temperature control

Personnel

Trained and competent staff

Test user is documented

Current SOPs readily available

Equipment

Maintained and serviced

Supplies

Uninterrupted supplies

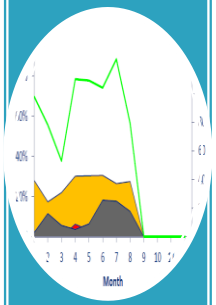
Appropriate transport and storage conditions

Specimens

Good quality

Labelled with unique ID

Completed request form



Internal quality monitoring

Test working properly

External Quality Assessment (EQA)

Lab's work checked by another lab

Accurate and timely reporting

Turnaround time

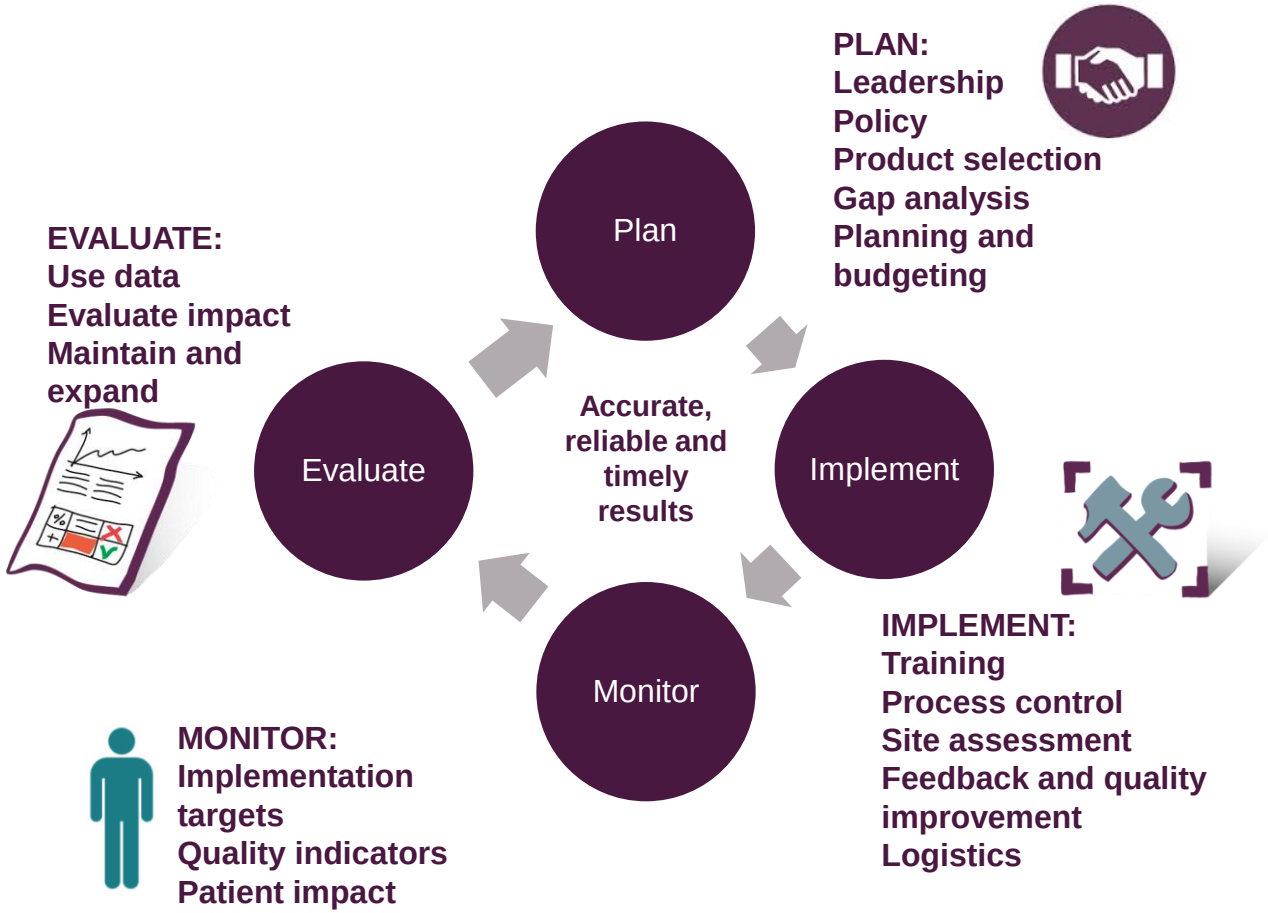
Results review

Accurate, reliable and timely results

Common challenges in operationalizing QA

- Lack of clear, standardised procedures
- Activities done inconsistently and/or not documented
- (on-site supervision, rechecking)
- Activities done, no result analysis, no feedback or corrective actions (quality indicators)
- Lack of equipment maintenance
- Poor budgeting for QA
- Lab and clinical quality indicators not integrated

Closing the gap: feedback for quality improvements

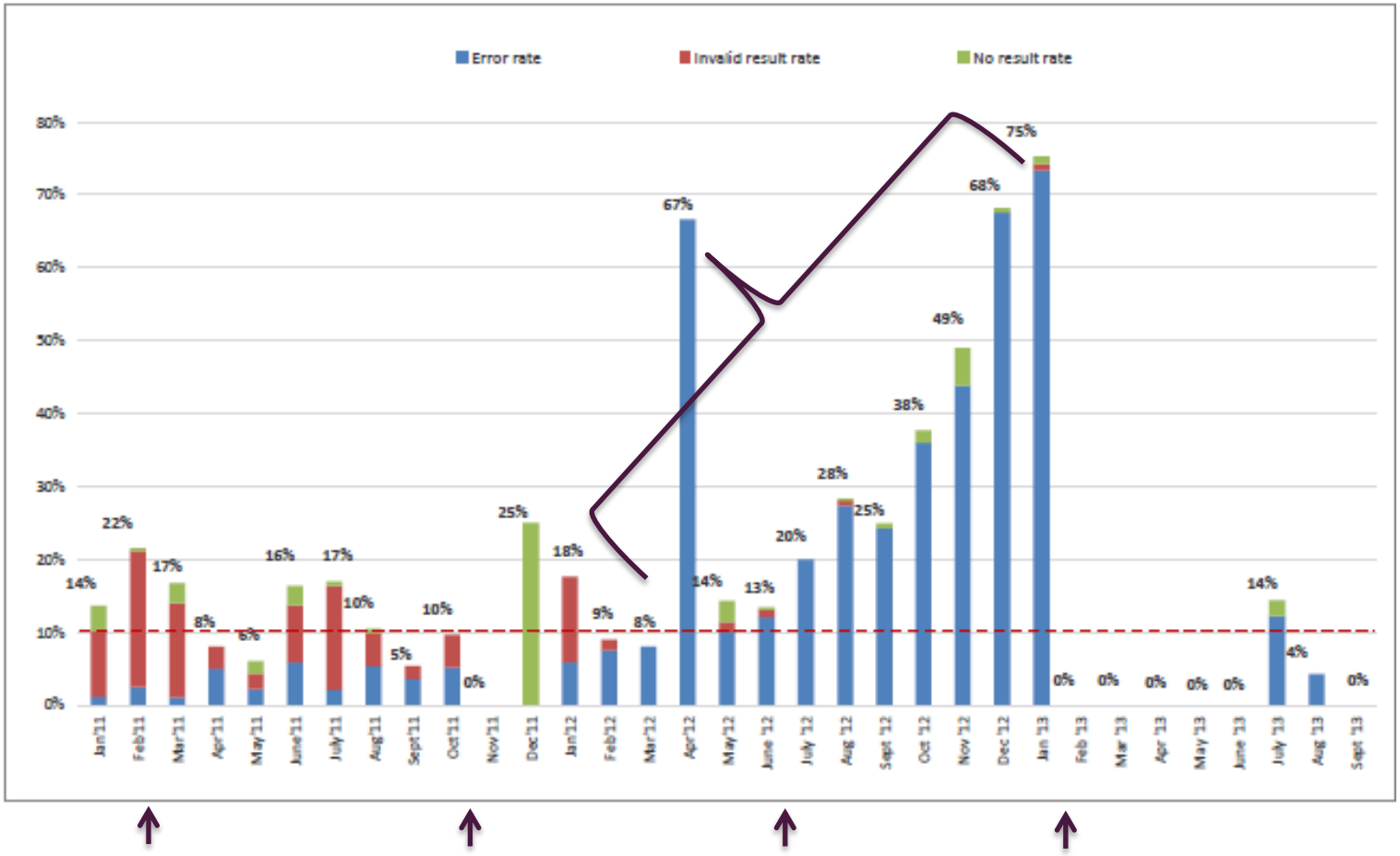


Quality assurance

- **User competency assessment**
- **Method validation**
- **Instrument verification**
- **Quality control**
- **New lot testing**
- **External quality assurance (assessment)**
  - Proficiency testing
  - Blinded re-checking
  - On-site supervision
- **Monitoring quality indicators**

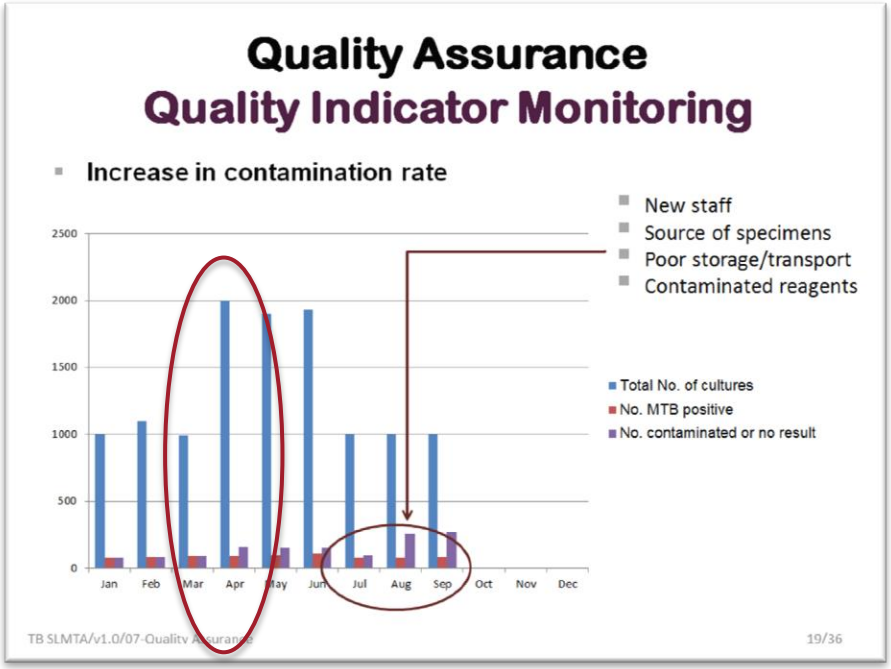
Overall Quality Management Systems approach

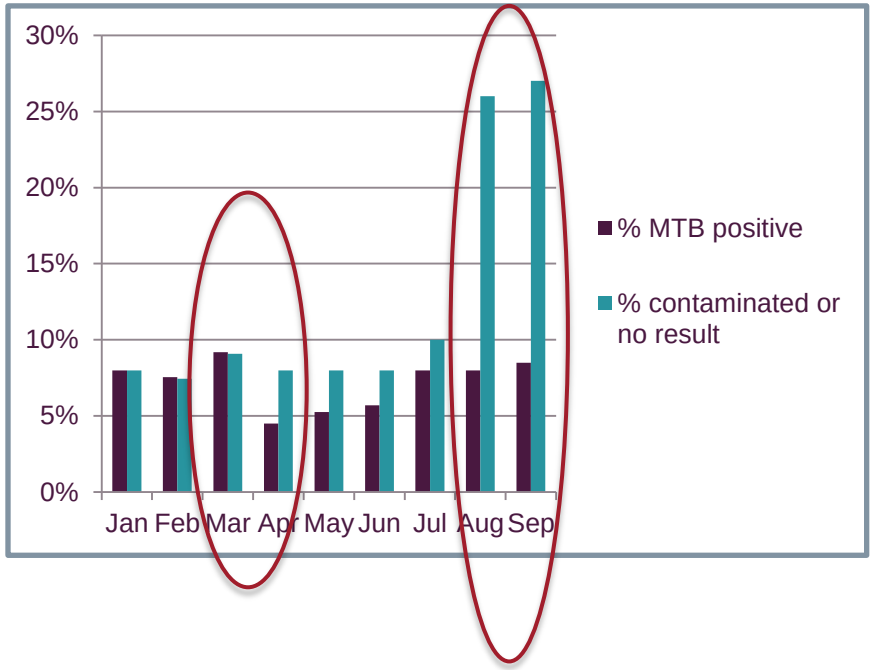
Missed opportunity for corrective actions



Understanding data for decision-making

- What does this graph show?





Site supervision

FIND
Because diagnosis matters

Quality Assurance Planning Tool

CLEAR DATA

On-site supervision

Regular on-site supervision is a key component of quality assurance for all laboratory tests.
This tool is intended to assist programme managers to plan human and financial resources required to conduct regular on-site supervision. The tool may be used by TB, H

> INPUTS		
Country of work	Tanzania, United Rep. of	← Enter the country you want to do the analysis for
Local currency	TZS	← This will autocomplete with the currency of the country selected above
Donor currency	USD	← Enter the currency of the funding agency / donor; or an alternate currency that will be used for budgeting purposes
Number of testing sites	4,000	← Enter the number of laboratories / testing sites to be included in the on-site supervision programme
Number of supervision visits planned per site each year	4.0	← Enter the intended number of visits to be conducted per site each year
Average length of each supervision visit (no. days)	0.5	← Estimate the average length of time (in days) to be spent at the testing site, excluding travel and preparation time
Average travel time per visit (no. days)	0.1	← Estimate the average length of time (in days) spent travelling to sites
Average time per visit spent on preparation, reporting and follow up (no. days)	0.2	← Estimate the average length of time (in days) spent preparing for each visit, completing the report and providing feedback and follow up to sites after the visit
Number of supervisors conducting each supervision visit	2	← No. staff conducting each supervision visit. Change this value if more than 1 supervisor/QA officer usually conduct each supervision visit together
Number of working days per year	250	← Change this value if the average number of working days per year in your country is different
Supervisor/QA officer per diem rate	80,000.00	← Use the recommended Ministry of Health per diem in the country for the staff level most commonly conducting on-site supervision. You can enter this information in the local currency OR in the donor currency.
Total transport cost per day for supervision (fuel, driver per diem, and other costs as applicable)	20,000.00	← Estimate the total cost of transport by adding the cost of fuel, driver per diem, and other costs as applicable. Adjust based on the country situation and usual mode of transport.

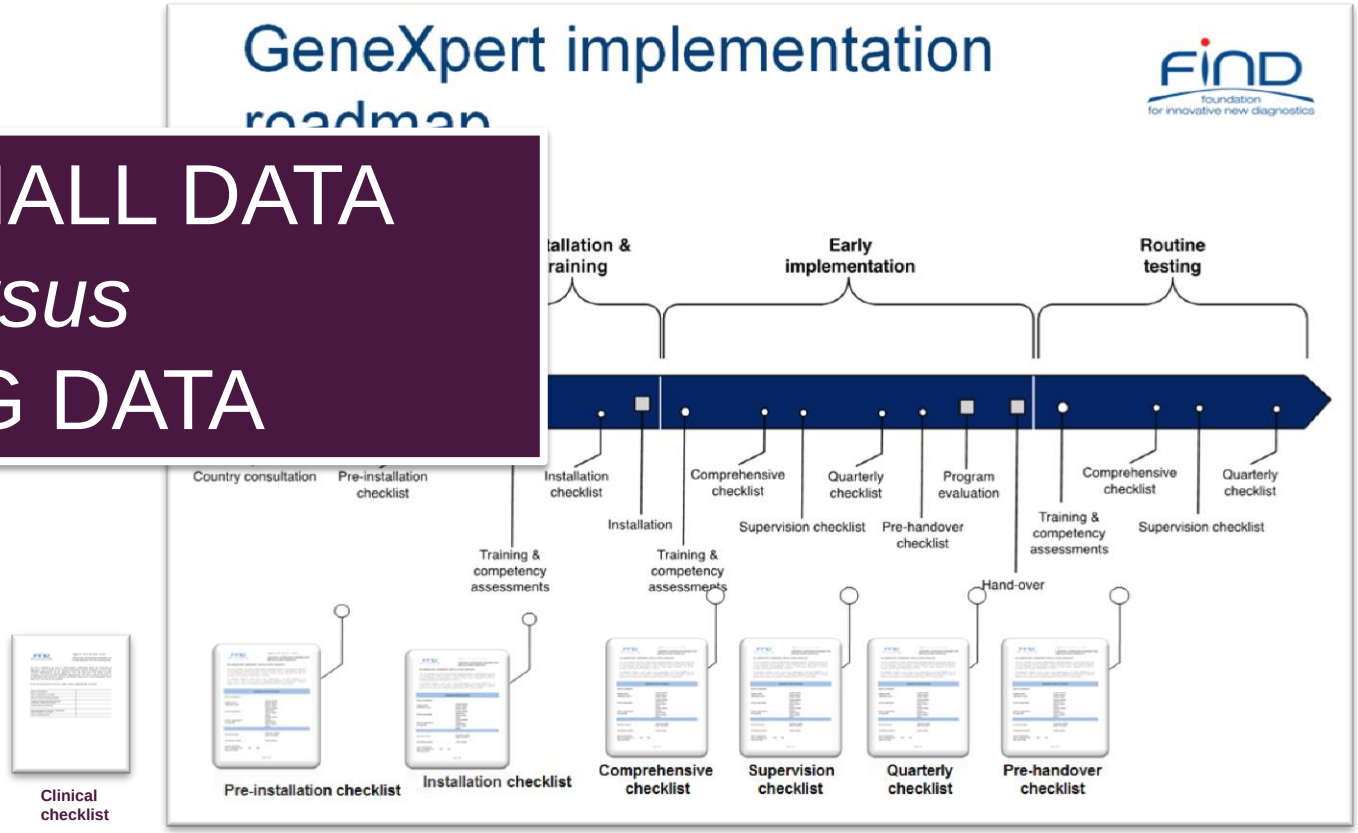
< OUTPUTS			
No. person working days per year needed for supervision visits	25,600		← Number of working days required to complete site visits each year
No. Quality officers needed for supervision	102.4		← Full time equivalent number of quality officers (assuming 100% time spent on supervision)
Annual cost of supervision visits	4,249,600,000,000 TZS	1,542,169 USD	← This the estimated total cost of running the on-site supervision component of the Quality Assurance programme for 1 year

No. person working days per year needed for supervision visits	640		← Number of working days required to complete site vi
No. Quality officers needed for supervision	2.6		← Full time equivalent number of quality officers (assur
Annual cost of supervision visits	169,984,000,000 TZS	61,687 USD	← This the e

On site-supervision: standardised checklists

- How to manage data?
- How to integrate all relevant QA data?
- Who needs what data for decision-making?

SMALL DATA
versus
BIG DATA

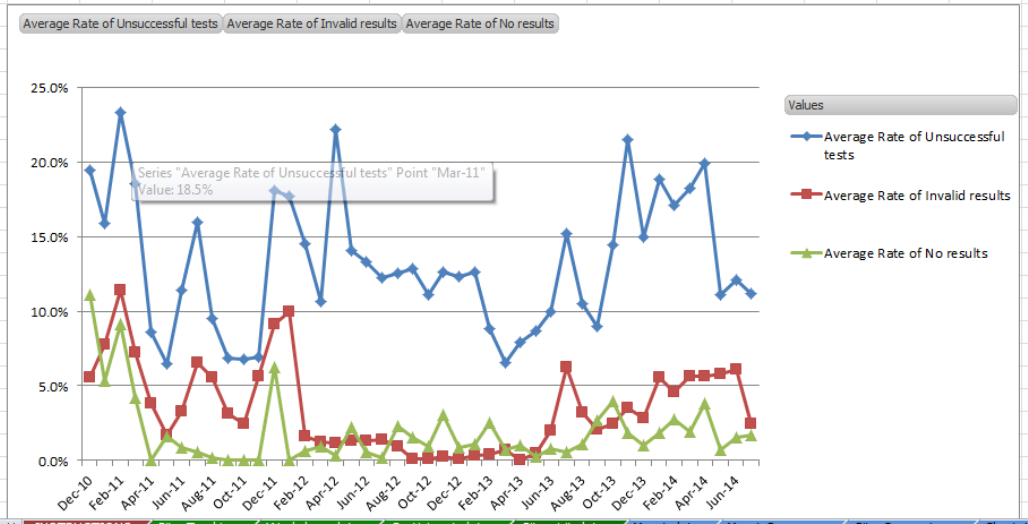


Integrated data

> Chart 2: Summary of errors

Refresh All

Year	Date	District	Regions	Site Name	Site type	Site Status	Supporting Partner
2010	Dec-10	0		Amana			FIND
2011	Jan-11		Dar es Salaam	Bagamoyo	Patients	Active	Ifikara
2012	Feb-11	Babati	Iringa	Bugando M...	Patients ...	Planned	KCRI
2013	Mar-11	Bagamoyo	Mara	Butimba Pri...	Prisoners	(blank)	Luthern
2014	Apr-11	Dodoma Re...	Mbeya	CTRL	Research		MMRC
2015	May-11	Dodoma Ur...	Pwani (coast)	Dodoma Re...	(blank)		MMRC ...
2016	Jun-11	Geita urban		Geita Distri...			NTLP
2017	Jul-11	Haydom		Haydom Lut...			PATH
2018	Aug-11	Ilala		Iringa			Pharma...
2019	Sep-11	Iringa urban		KCRI			UMB/M...
2020	Oct-11	Kinondoni		Keko Prison...			USAID
	Nov-11	kyela		Kibong'oto			
	Dec-11	Lindi munic...		Kyela			
	Jan-12			Ligula Hosp...			
	Feb-12			Lugalo Milit...			
	Mar-12			Maweni Re...			
	Apr-12			Mbeya Ref...			
	May-12			Mbeya Regi...			



INSTRUCTIONS | Site Tracking | Workshop data | Participant data | Site visit data | Xpert data | Xpert Summary | Site Comparison | Chart 1 - Testing | **Chart 2 - Errors** | Chart 3 - Usage | CTRL ONLY

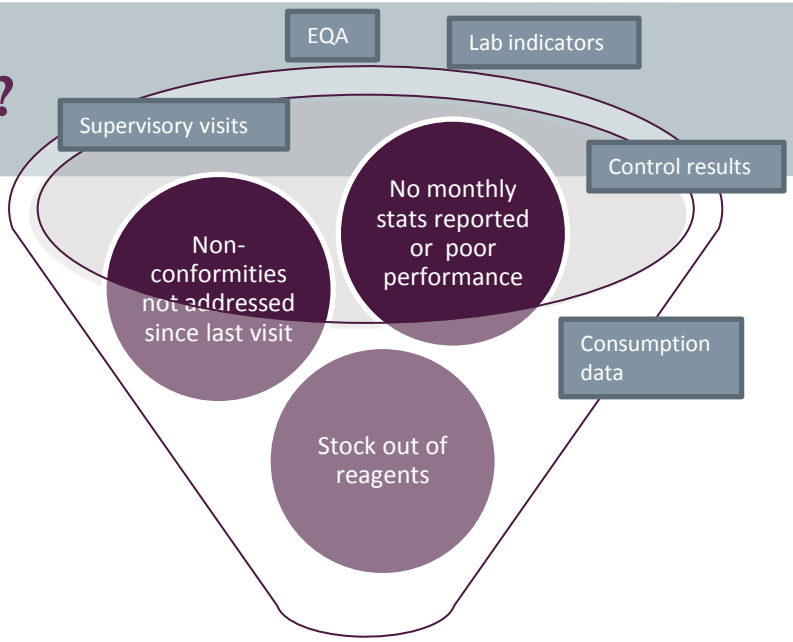
How to make QA data work?

Aim for a comprehensive tool to integrate data from:

Site visits: non-conformities, corrective actions and feedback

EQA results and corrective actions

Monthly lab statistics (use to target poorly performing sites for on-site supervision)



Integrated reporting

Targeted expert supervision to individual labs

Management and systems issues across labs

Better feedback to labs for quality improvements

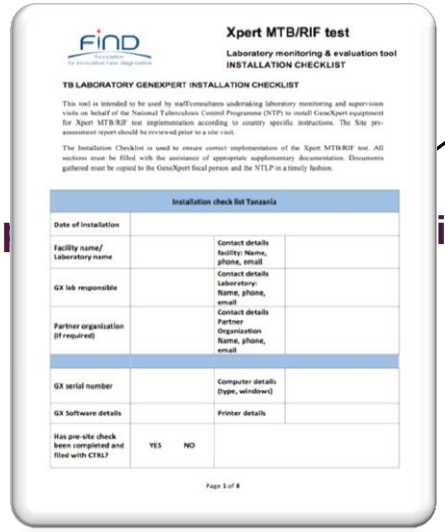
Impact of doing/not doing QA

- **How to measure impact?**
  - to ensure uptake of recommended activities
  - To motivate for need and funding among MOH, donors and partners
- **What is the cost of not doing QA?**

- **Tools to ease the reporting and data management burden and assist in interpretation of problems and corrective actions**
- **Systems approach**
- **Learn from laboratory –based QA programmes to expand to non-laboratory settings**

Maintenance

- **Who is responsible for maintenance?**
  - MOH (NTP, NACP)
  - Individual facilities
  - Partners
- **How to coordinate?**
- **Technical support by supplier**
- **Remote calibration**
- **Maintenance contracts versus module rep ilure**
  - Costing analysis
  - Service interruption



Xpert MTB/RIF test

Laboratory monitoring & evaluation tool
INSTALLATION CHECKLIST

TB LABORATORY GENEXPERT INSTALLATION CHECKLIST

This tool is intended to be used by staff/consultants undertaking laboratory monitoring and supervision visits on behalf of the National Tuberculosis Control Programme (NTP) to install GeneXpert equipment for Xpert MTB/RIF test implementation according to country specific instructions. The Site pre-assessment report should be reviewed prior to a site visit.

The Installation Checklist is used to ensure correct implementation of the Xpert MTB/RIF test. All sections must be filled with the assistance of appropriate supplementary documentation. Documents gathered must be copied to the GeneXpert focal person and the NTLP in a timely fashion.

Installation check list Tanzania			
Date of installation			
Facility name/ Laboratory name		Contact details facility: Name, phone, email	
GX lab responsible		Contact details Laboratory: Name, phone, email	
Partner organization (if required)		Contact details Partner Organization Name, phone, email	
GX serial number		Computer details (type, windows)	
GX Software details		Printer details	
Has pre-site check been completed and filed with CTRL?	YES NO		

Page 1 of 8

Pre-handover checklist

Maintenance culture

- **Among countries, people and donors**
- **Funding for equipment maintenance**
- **What data do we have to show impact of doing / not doing maintenance?**

  Is maintenance cost-effective?

Original Article

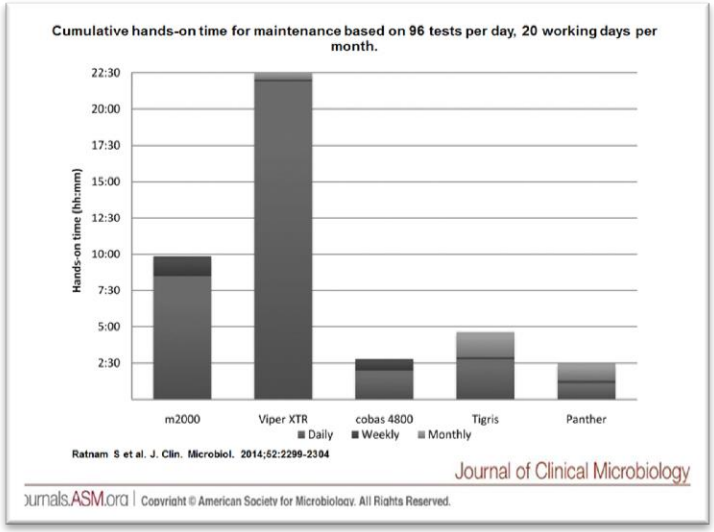
Lack of Maintenance of Shortwave Diathermy Equipment Has a Negative Impact on Power Output

Rinaldo Roberto de Jesus Guirro, PhD[1, 2)*], Elaine Caldeira de Oliveira Guirro, PhD[1, 2)], Natanael Teixeira Alves de Sousa, PT[2)]

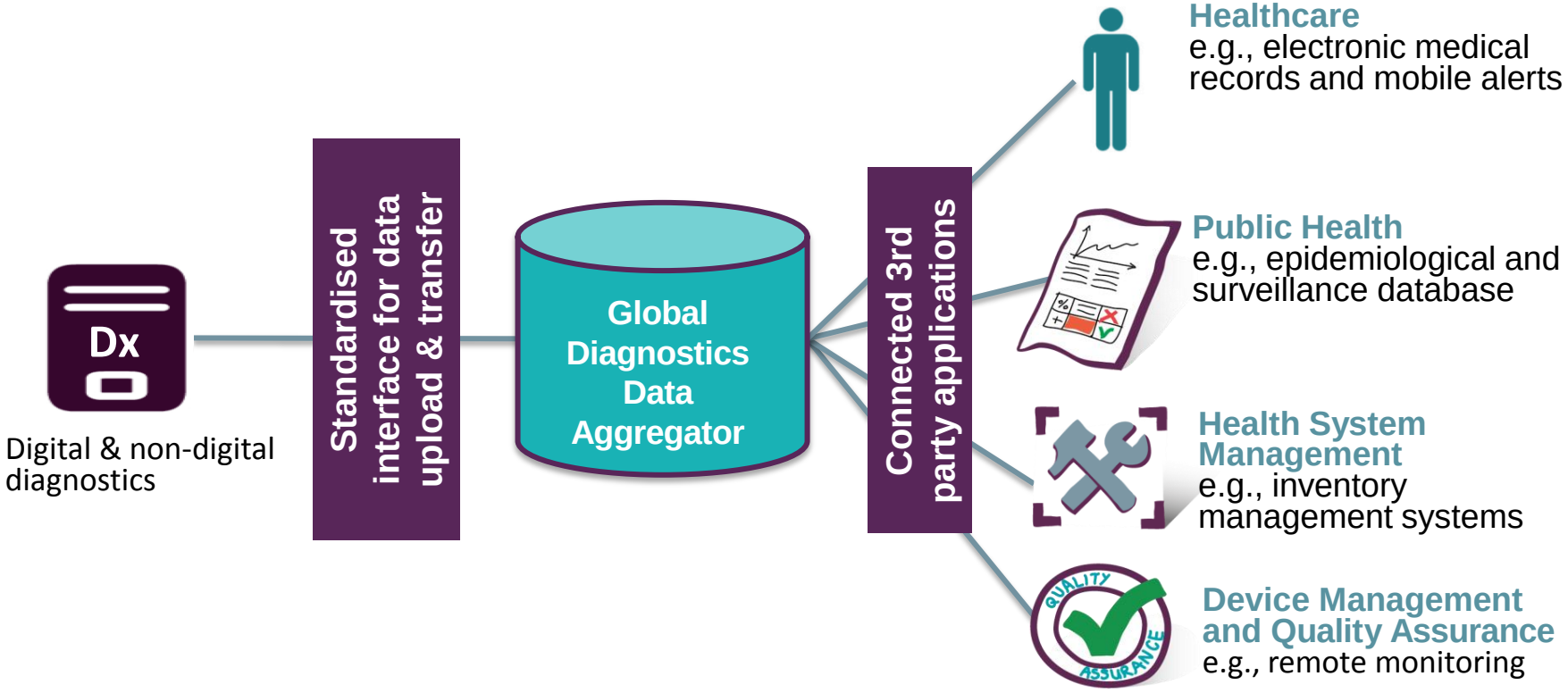
[1)] *Laboratory of Physiotherapeutic Resources, Department of Biomechanics, Medicine and Rehabilitation of the Locomotor System, Laboratory of Physiotherapeutic Resources, Ribeirão Preto Medical School of University of the São Paulo: Bandeirantes Avenue, 3900, Monte Alegre CEP 14,049-900, Ribeirão Preto, SP, Brazil*

[2)] *Post-Graduation Program in Rehabilitation and Functional Performance, Ribeirão Preto Medical School of the University of São Paulo, Brazil*

J. Phys. Ther. Sci.
26: 557–562, 2014

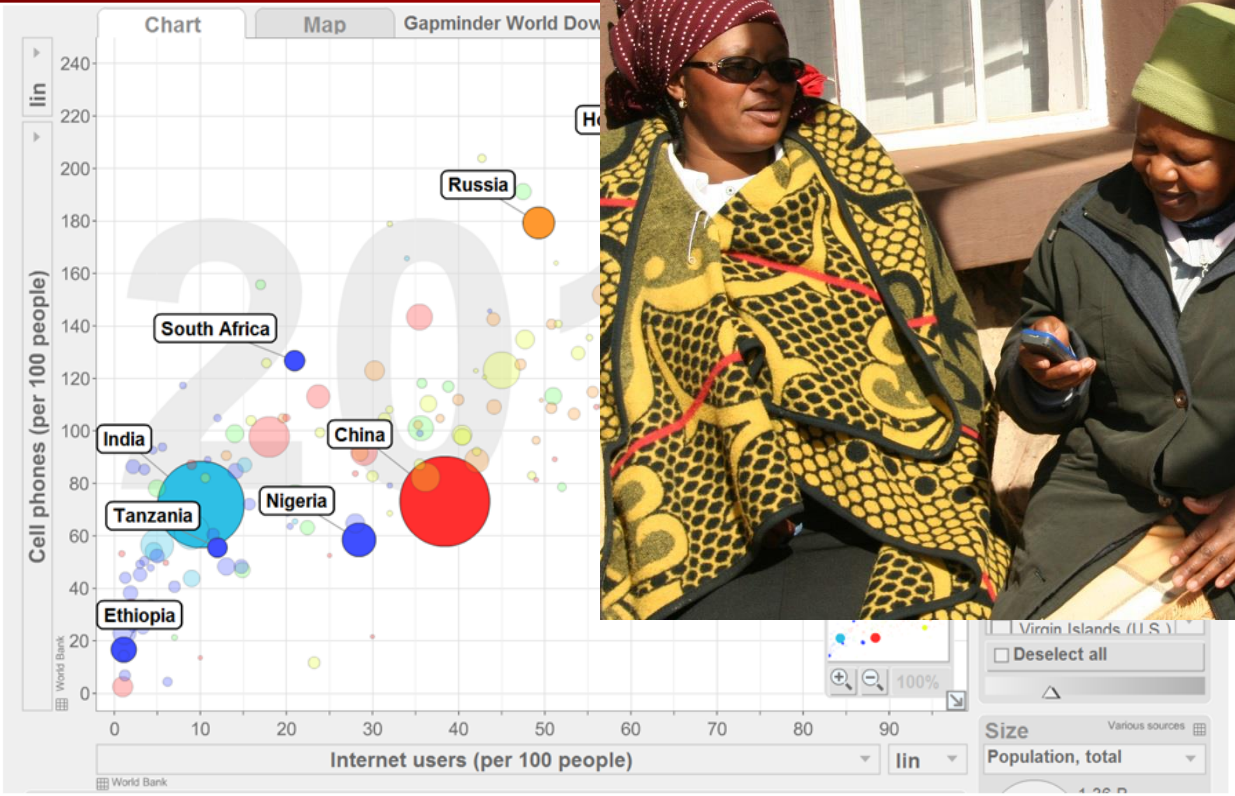


Our vision for connected diagnostics to help maximize impact



Access to mobile technology

Connectivity – cell phones
internet use (limited broa



Ref: Gapminder World. www.gapminder.org/world-offline

To all our partners, donors and patients…

THANK YOU

FIND
foundation for innovative new diagnostics

Australian Government
AusAID

Bill & Melinda Gates foundation

CDC
Centers for Disease Control and Prevention

DFID
Department for International Development

Development Cooperation
Ministry of Foreign Affairs

USAID
From the American People

DNDi
Drugs for Neglected Diseases initiative

UNITAID
Together to Heal

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

kfw
Entwicklungsbank

National Institutes of Health

Stop TB Partnership
TB REACH

World Health Organization

UBS
UBS Optimus Foundation

UKaid
from the British people